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09/811,075	03/16/2001	Carl Arne Krister Borrebaeck	BIOT 100	6298

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EXAMINER
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WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 03/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/811,075

Applicant(s)

BORREBAECK ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 27-37 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 27-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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**DETAILED ACTION**

***Election/Restrictions***

Applicant's election with traverse of Group I in Paper No. 8 is acknowledged. The traversal is on the ground(s) that with the amendments to the claims, the claims directed to groups I and II do not provide for different method steps and/or end results. Applicants also traverse that to be valid, a restriction requirement must establish both that (1) the inventions are either independent or distinct and (2) examination of more than one of the inventions would constitute a burden to the examiner. This is not found persuasive because the amended claims are still directed to independent and distinct invention. Because these inventions are independent and distinct, examination of each invention would impose undue burden to the examiner. Group I, drawn to a method of making an array is distinct from the newly presented claims 27-37. However, amended claims 2 and 9, which now depends on the elected group I will be examined.

The requirement is still deemed proper and is therefore made FINAL.

Applicants' election of the species, antigen binding variant is noted and acknowledged.

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Claims 10 (species, nucleic acid) and newly presented claims 27-37 (drawn to a distinct and independent method of isolating ligands) are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

***Status of Claims***

Claims 1-9 and 11-13 are under examination.

Claims 14-26 have been cancelled with the Present Amendment.

Claims 10 and 27-37 are withdrawn from further consideration, as stated above.

***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

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### ***Specification***

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Claim Objections***

Claim 7, last line is objected to because the lines are crowded to close together (almost superimposed) to the first line of claim 8 making reading and entry of amendments difficult. Also claim 8, last line with claim 9, first line. A substitute claim with lines one and one-half are required. See 37 CFR 1.52(b).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 and 11-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not

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described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to provide an adequate description for the claimed method using any kind of "ligand", "anti-ligand", "library", "replicable unit" and "mixture of ligands". The specification, including the Examples, presents a general statement of making an array of the ligand and anti-ligand reaction. It is not apparent from the Examples whether a specific ligand/anti-ligand has actually been made. This is made more complex in view of applicants statement at page 3, lines 20-29. It states that "despite the potential benefits of methods of studying protein expression, the identification of proteins poses much greater problems than the identification of DNA. **Even if the primary structure of a particular protein is known, knowledge of what molecules will specifically bind to the protein, and therefore serve as a probe for that protein, cannot be predicted.....**" (Emphasis added).

The generalizations made in the specification and a mere laundry lists of ligand and anti-ligand do not equate to an adequate description for the claim. The claim contains too numerous undefined or unknown variables.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 and 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the steps between (iii) and (iv) i.e., the steps by which isolation is based. The method steps are unclear as to the determination of occurrence of binding made based simply on the "providing" and "exposing" steps. "The number" lacks antecedent support from the preceding steps. It is unclear as to the metes and bounds of this number. It is not clear as to the components present in a preparation of anti-ligand. The metes and bounds of the recited "preparation" and "plurality of different anti-ligands", within the context of the claim, are unclear.

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B. It is suggested that "A" in the preamble of claims 2-9 and 11-13 be changed to "the". Claim 1 already recites a method.

C. Claim 3 is unclear as to step and need of separating the mixture of ligands prior to exposing to the library.

Furthermore, it is unclear as to the "basis of one or more parameters" by which the mixture of ligand is separated. This claim broadens the base claim. The metes and bounds of "one or more parameters" are unclear, as to the measure by which it is based on.

D. Claim 4 is unclear. Separation by 2-D gel electrophoresis is not a parameter. This is a broadening of the base claim. The additional step of separation by 2-D is not recited in the base claim.

E. Claim 5 broadens the base claim. The base claim does not recite a step for immobilization of a separated mixture of ligands.

F. Claim 7 is indefinite as to what constitutes a "replica" of the 2-D gel, within the context of the claim.

G. Claim 9 is unclear as to the metes and bounds of the "variant or derivative" of an antigen binding antibody.

H. Claim 11 is indefinite as to the basis by which "at least some of the ligands and/or anti-ligands" are unknown.



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"And/or" is unclear as the basis by which both are unknown or unknown.

I. Claim 12 is rejected for the same reason as Claim 11, above. The term "substantially" is indefinite, especially in the absence of positive recitation in the specification.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-9, 11-13 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wagner et al (6,329,209).

Wagner discloses at col. 3, line 58 up to col.4, line 16 a method for producing an array of protein-capture agents( anti-ligand as broadly claimed) comprising a first step of selecting protein-capture agents from a library of protein-capture agents, wherein the protein-capture agents are selected by their binding affinity to proteins which are the expression products, or fragments thereof, of a cDNA expression library. The second step of the method comprises producing a plurality of purified samples of the protein-capture agents selected in the first step. The third step comprises immobilizing the protein-capture agent of each different purified sample onto an organic thin film on a separate patch on the substrate surface to form a plurality of patches of protein-capture agents on discrete, known regions of the surface of a substrate.

Wagner further discloses at col. 12, lines 9-40 that the binding partners of some or all of the protein-capture agents on the array need not necessarily be known. The binding partner of a protein-capture agent of the array may be a protein or peptide of unknown function. The different protein-capture agents of the array may together bind a wide range of cellular proteins from a

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single cell type, many of which are of unknown identity and/or function. Wagner teaches at col. 13, lines 6-35 that the protein-capture agents are antibodies or antibody fragments. The antibodies or antibody fragments of the array may optionally be single-chain Fvs, Fab fragments, Fab' fragments, Fv fragments, dsFvs diabodies, Fd fragments. The antibody fragments have been derived by selection from a library using the phage display method (step i, as claimed). The antibody fragments are derived individually by selection based on binding affinity to known proteins, wherein, the binding partners of the antibody fragments are known. The antibody fragments have been derived by a phage display method comprising selection based on binding affinity to the (typically, immobilized) proteins of a cellular extract or a body fluid (step ii, as claimed). In this respect, some or many of the antibody fragments of the array would bind proteins of unknown identity and/or function. The detailed method and components used in the method is presented in the Examples 1-7, col. 38 up to col.44.

Wagner's disclosure reciting specific method steps and components of the process steps anticipates the broad claimed method and components or renders obvious the broad claimed methods, which is subject to several broad interpretations.

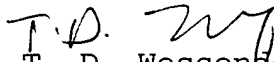
No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

tdw  
February 21, 2003